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Non-Invasive Pneumothorax Detector

**PRINCIPAL INVESTIGATOR:**

Alan J. Greszler, M.S.CHE

**CONTRACTING ORGANIZATION:**

ElectroSonics Medical

Cleveland, Ohio 44114

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14. ABSTRACT A small portable hand-held device has been developed to assist in the detection of a pneumothorax far forward in the battlefield. The system uses Micropower impulse radar to scan the torso in eight specified locations to detect the location (left or right lung) of a suspected pneumothorax. Product development has been completed and the system has been transferred into manufacturing. All verification testing has been completed and the system is ready for pivotal clinical studies to satisfy the regulatory requirements for sale and distribution of the product in the U.S. market.					
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## Contents

Introduction: .....	4
Military Relevance: .....	4
Body: .....	5
Objective 1: Hardware Integration .....	5
Objective 2: Software Development.....	7
System Verification Testing: .....	9
Manufacturing Transfer: .....	9
Objective 3: Human use study .....	9
Key Research Accomplishments .....	10
Reportable outcomes.....	10
Conclusions .....	10
References .....	10
Appendices.....	10

## Introduction:

This document represents the annual report for work performed by ElectroSonics Medical under a grant through the United States Army Medical Research and Materiel Command (USAMRMC). The technical objectives that form the scope of work support the development and clinical testing of a non-invasive pneumothorax detector. Goal and objectives are reflected in the formal approved grant. Uncertainty in the current and near-future computational devices carried by the medic made it prudent to develop a PTX detector that will operate on a surrogate computational device. As there are many possible insertion points of the PTX detector technology, it is more important to maintain a flexible interface that can be easily adapted to the different medical devices along the continuum of care.

Note: Since the submission of the initial proposal, ElectroSonics Medical, Inc has created a wholly-owned business unit called PneumoSonics to carry out the development of their pneumothorax detector. In this document ElectroSonics and PneumoSonics will be used interchangeably.

## Military Relevance:

Pneumothorax (PTX) continues to be a leading cause of preventable death on today's battlefield. It has proven to be very difficult to quantify the causes of death on the battlefield. Studies to date have retrospective in nature. This consists of reviewing data in repositories such as the Wound Data and Munitions Effectiveness Team database. Work by Bellamy [1] and Champion [2] indicate that tension pneumothorax is the cause of death in 10% and 5% of soldiers killed in action in Vietnam and Operation Desert Storm respectively.

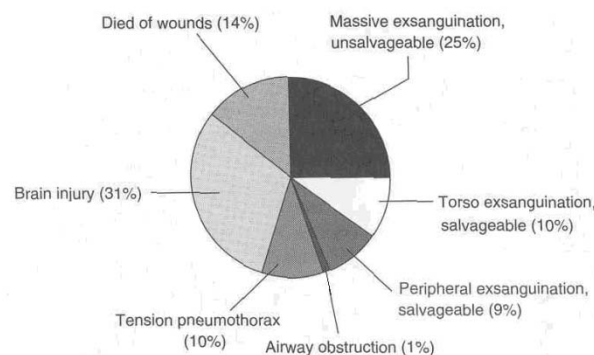


FIGURE 1-1 Distribution of fatal battlefield injuries in Vietnam. SOURCE: Adapted from Bellamy (1984, 1987a,b, 1995).

In Congressional testimony, Air Force Surgeon General George P. Taylor stated that “pneumothorax is a combat killer.” General Taylor went on to explain that medics were issued angiocath needles to perform life-saving needle thoracentesis in the case of tension pneumothorax.<sup>1</sup> Tension pneumothorax is a life-threatening condition that requires immediate treatment. This condition can grow out of a simple non-threatening pneumothorax spontaneously. Current practice today in the Special Forces includes the placement of a chest tube by the medic (a difficult and dangerous procedure for a medic in the field) in all cases of penetrating thoracic injury before evacuation.

Pneumothoraces are very difficult to diagnose even in the hospital setting. A civilian postmortem study found 77 cases of pneumothoraces in a population of 3,500 patients. Of these 77, almost half (37 patients) were undiagnosed [3]. Iatrogenic pneumothoraces (due to medical care or medical procedures) remain a problem. During 2000-2002, 33,571 cases (1.011 per 1,000 hospitalized at risk patients) of iatrogenic pneumothorax occurred in the US, resulting in 6,234 deaths (18.57%) [4]. The rate for combat support hospitals and forward surgical teams is not known, but is likely to be greater.

Work by Army medical researchers has determined that a simple needle decompression technique can be performed by the medic in cases of life-threatening pneumothorax. However in the field and in the hospital, a simple device to detect pneumothorax and also detect the reinflation of the lung after needle thoracentesis or chest tube placement would be of great benefit to the Army and save lives of soldiers.

Since 1995, MRMC has funded research into the development of a small low-powered device that medics could use to detect PTX. The work laid out in this document represents part of the effort in this area.

### **Body:**

Working with technology from Lawrence Livermore National Labs (LLNL), ElectroSonics Medical, Inc. (EMI) has developed pneumothorax detection devices based on patented Micropower Impulse Radar (MIR) technology. This device emits very low power radio frequency impulses of a very high frequency and broad spectrum (1-4 GHz). The resultant echoes are collected by extremely high-speed circuitry and analyzed by a proprietary software algorithm. EMI has miniaturized the MIR electronics and developed the software to allow the detector to operate on a multitude of host platforms. All power is drawn from the host, therefore no additional power sources are necessary. The PnuemoScan consists of a handheld sensor which includes the MIR circuitry and antenna. This sensor will transmit the received signals to the operating computer platform for processing.

### **Objectives:**

During the first year of development we have completed the miniaturization and integration of the MIR electronics. The PTX detector has been designed to operate in conjunction with any number of computational devices in use at the time by military medics and clinicians throughout the continuum of military clinical care. Each specific research task as defined in the proposal will be addressed in this report. This will include design of a miniaturized MIR board to include the complex integration of analog and digital electronics on a single board, software engineering necessary to port the code to a portable computing device and the development of a graphical user interface. Finally a phase 2-type human use trial to demonstrate the safety and efficacy of the system will be completed as part of the regulatory requirements to allow distribution of the product.

### **Objective 1: Hardware Integration**

The key design efforts were to translate the MIR circuitry to a smaller platform, redesign the antenna and board to meet the advanced environmental testing for air worthiness, and integrate the system into a suitable housing to meet the military requirements for portability, ruggedness,

and size. Based on feedback received from the end military user, the system is a cable tethered unit that provides access to all eight scan locations, allows one-handed operation, and is small enough to fit into an existing side pouch on the medic pack.

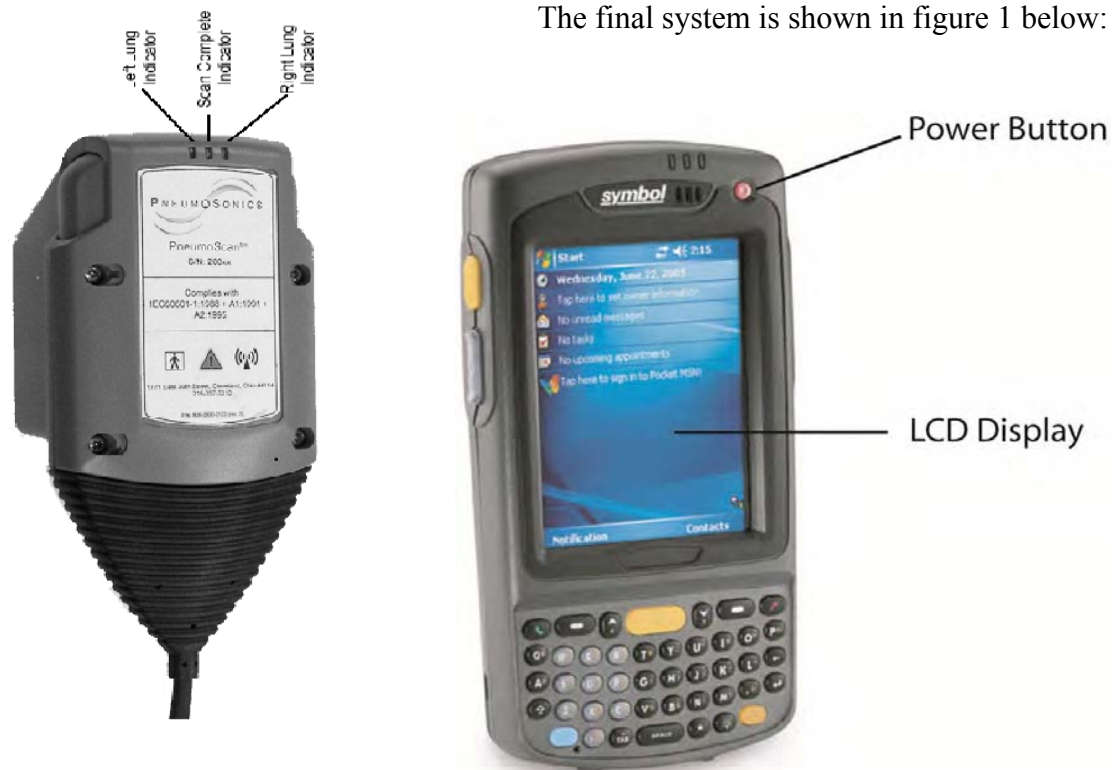


FIGURE 1: PneumoScan and MC75 Operating Platform

The PneumoScan device on the left contains the complex Ultra Wide Band (UWB) electronics to perform pneumothorax detection. This unit can be interfaced with any computing platform meeting the minimum system requirements. Shown is the MC75 handheld computer by Motorola. This system is currently deployed by the military and was intended to be carried by field medics. PneumoSonics utilized this platform for all system verification testing.

The PneumoScan is a rugged device that has been designed to handle the extreme conditions that it may encounter in field use. The electronics were developed with highly stable components that allow the system to operate over a -20C to 40C temperature range. The housing has overmolded gaskets that provide an air and water tight seal preventing ingress of damaging liquids and dust. The PneumoScan is molded of a reinforced polycarbonate material that is routinely used in surgical instruments. The PC provides the toughness to handle multiple drops of the unit and is biocompatible so that the interface with the user and patient does not cause any issues. The PneumoScan unit is seam-free where the patient is contacted and has no exposed fasteners or screws.

Internal to the housing is the MIR horn antenna. This subsystem was redesigned to be durable and can withstand the aggressive environments. The antenna/board assembly has been vibration tested over the entire frequency band with no damage or degradation.

#### Cable design:

The PneumoScan draws all operating power from the host computing system. It is tethered with a custom-designed cable that is rugged and durable. Figure 2 shows the two versions of the cable that have been designed for use with the PneumoScan. On the left is the custom cable exclusively for use with the MC75 handheld computer. On the left is the universal serial bus (USB) connector version that allows the PneumoScan to be used on a standard computing platform with a USB 2.0 connector.



FIGURE 2: Two configurations of the cable for connecting the PneumoScan to various computing platforms.

#### **Objective 2: Software Development**

Significant effort has been expended to upgrade and convert the software to run on different platforms. The software and firmware was written to comply with IEC 60601-1-4 so that it could be easily verified and can be modified in the future as we expand the use of the device for other applications.

In addition, we have optimized the algorithm and user interface. The improved algorithm provides more rapid feedback to the medic. The new user interface provides both tactile and visual feedback to the medic on the MIR/antenna system as well as provides the information graphically on the surrogate platform. The PneumoScan is readily deployed with minimal training to the user. In figure 3 the eight scan points on the torso are displayed.

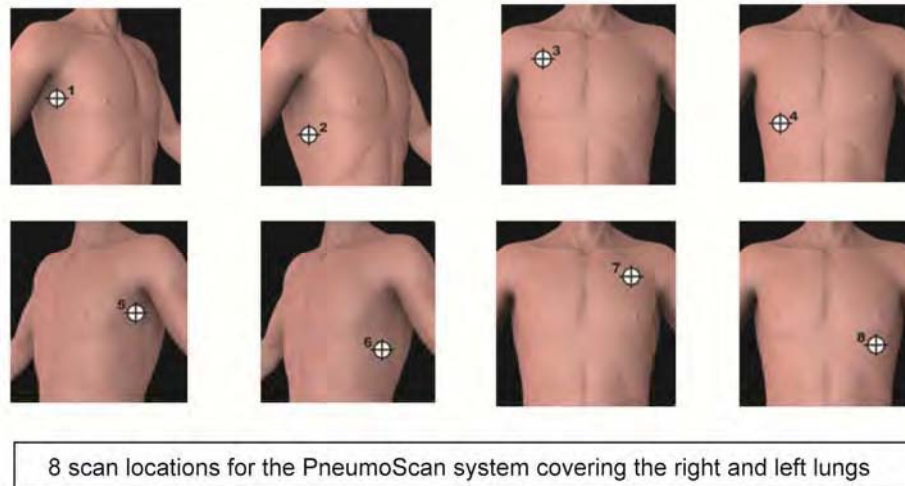


FIGURE 3: Eight predefined scan locations are required for the PnemoScan detector

These eight scans are graphically displayed to the user with directions to scan the location. When the scan is complete an audible sound indicates that the PnemoScan can be move to the next location. When all eight scans are completed, an audible sound is made and the results are displayed on the computing platform screen. If the scan was successful without any errors, then one of four possible results are displayed. These are shown in Figure 4 below:

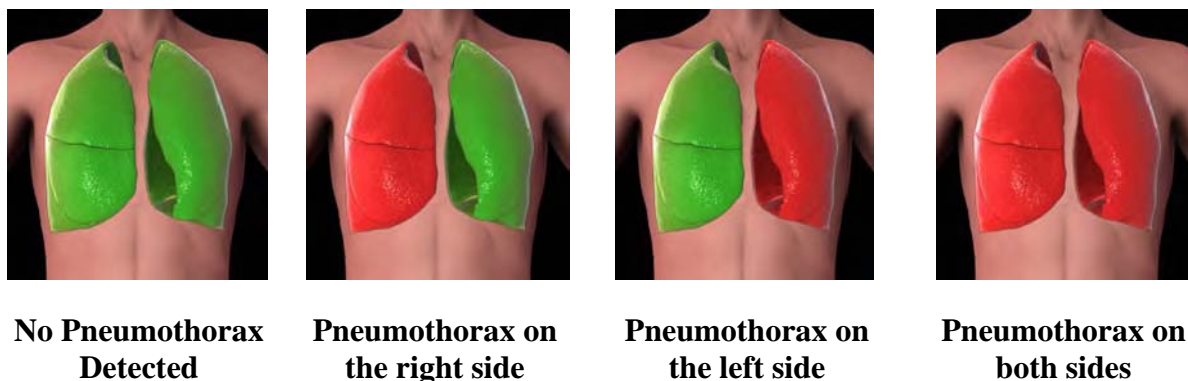


FIGURE 4: Possible outcomes of a successful PnemoScan read.

This simple user interface provide easily interpreted results in less than a minute, allowing the medic to quickly assess the patient's condition and determine the best course of treatment.

The algorithm has been expanded and improved over the initial approach for the civilian device. Using windowing and cross-correlation techniques, the sensitivity to a pneumothorax has been improved. In addition, several system checks have been added to insure the device is functioning as expected prior to a scan. Lastly, the algorithm detects if the PnemoScan was not placed properly onto the patient and requests the user to perform a new scan.



**System Verification Testing:**

We have completed extensive testing of the system for safety and reliability. This includes external testing to demonstrate compliance with the international standards for medical devices:

1. IEC 60601-1-1 – General Requirements for Safety
2. IEC 60601-1-2 – Electrical Safety and Emissions
3. IEC 60601-1-4 – Software Compliance
4. Extended Radar testing
5. Ingress of Fluids and Dust Evaluations to IP54 Rating
6. Extensive Thermal Analysis Evaluations

In addition, we have completed a formal design verification testing including all shipping and drop tests, vibration analysis, and system compliance testing against the design specifications. A complete hazard analysis, Risk Analysis, and Failure Modes and Effects Analysis (FMECA) have been completed. To date, the system has successfully passed all verification tests. The final testing required for military use is the formal airworthiness testing which will be completed in the second year of the program.

**Manufacturing Transfer:**

The design was completed and transferred into an ISO 13485 certified manufacturing facility. A production run was completed for the PneumoScan. This allowed the device to be submitted for a CE Mark to allow distribution in the European community. This will allow clinical evaluations to be started sooner than possible in the United States due to FDA regulations.

**Objective 3: Human use study**

The third and final objective of this program was to complete clinical evaluations in a trauma setting. We have initiated discussions with the regulatory agencies (FDA) to allow us to proceed with clinical evaluations. This has proved to be a significant challenge due to the unique technology utilized in the PneumoScan. Since there are no systems currently approved that claim to be able to detect a pneumothorax, the device has been classified as Class III medical product and must follow the Premarket Authorization (PMA) process for clearance.

After extensive discussions with the agency, we have decided to proceed with a surgical study based on Lung Biopsy procedure that has a high incidence of inducing a pneumothorax. This will allow us to gain regulatory clearance to market the product in the U.S.

We have also initiated studies at Massachusetts General Hospital to evaluate the system in a trauma setting. Working with Dr. Marc DeMoya, we will use the PneumoScan on patients presenting to the E.D. with blunt or penetrating chest injury. Working under the IRB process, we will be able to assess the safety, efficacy, and usability of the product.

Additionally we have entered into discussions with the German military to begin evaluation of the system.

## **Key Research Accomplishments**

1. Develop Input Specifications, FMEA
2. Completed Electronic Hardware Development
3. Optimized the Detection Algorithm
4. Completed System Verification Testing
5. Initiated Military Testing for Air Worthiness Evaluation
6. Completed EN60601 Testing for ISO Certification and CE MARK
7. Initiated discussions with the FDA Regarding Clinical Testing
8. Started Trauma Study to evaluate System at Mass General Hospital

## **Reportable outcomes**

Based on this research at this time there are no reportable outcomes. PneumoSonics intends to apply for further funding to support expanding the applications of MIR technology into other diagnostic areas. These include hematoma detection, pneumothorax volume detection, and vital signs monitoring. These technologies can be developed using the existing platform with expanded software and new algorithms.

## **Conclusions**

PneumoSonics Inc. (PSI) has developed and is clinically testing a portable medical device, PneumoScan™, to rapidly detect the presence of a pneumothorax. PneumoScan is non-invasive and provides timely, objective results on the presence and location of a pneumothorax. In feasibility clinical human testing PneumoScan accurately detected the presence of pneumothorax with 93% sensitivity and 85% specificity. The device is portable, easy to use, requires minimum training to operate and provides objective results in less than one minute that do not require any interpretation.

The device has completed all verification testing and is ready for manufacturing. Final airworthiness system evaluation must be completed as well as the pivotal clinical evaluations required by the regulatory agencies prior to release for use by U.S. military personnel. These will be completed in the second year of the program.

## **References**

1. Presentation by Lieutenant General (Dr.) George Peach Taylor Jr., Air Force Surgeon General to the Military Personnel Subcommittee of the House Armed Services Committee, October 19, 2005.
2. Belamy RF, The Causes of Death in Conventional Warfare. Military Medicine, Feb 1984
3. Champion HR, A Profile of Combat Injury. J of Trauma, May 2003
4. Ludwig J, Pneumothorax in a large autopsy population. A study of 77 cases. Am J Clin Pathol Jul 1978
5. Patient Safety in American Hospitals, Health Grades 2004
6. Holcomb, J. B. et al., Efficacy of Needle Thoracostomy for Relieving Tension Pneumothorax in an Anesthetized Porcine Model. 1999. Unpublished Work.

## **Appendices**

N/A